United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-96-030 November 1996

R.E.D. FACTS

S-Kinoprene

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 4117, S-Kinoprene.

Use Profile

S-Kinoprene is a biochemical pesticide which is chemically synthesized and used as an insect juvenile hormone analog on indoor non-food/non-feed crops, including ornamental plants grown in greenhouses and interiorscapes. S-Kinoprene, applied at a low rate, inhibits normal insect growth during the molting process causing morphogenic, ovicidal, and sterilization effects. When applied at a higher rate, S-Kinoprene kills the adult populations of insects such as aphids, whiteflies, mealybugs, fungus gnats, and armored scales. Since S-Kinoprene is used on non-food/non-feed crops, a food tolerance establishment/exemption is not an issue.

Formulations include the technical grade active ingredient (TGAI) of 89% synthetic S-Kinoprene and 11% related impurities. The only end-use product, Enstar®II (EPA Reg. No. 55947-82) consists of 65.1% TGAI and 34.9 inert ingredients.

S-Kinoprene is applied to 3,200 acres of ornamental plants in greenhouses and interiorscapes with 70% total usage in the States of California and Texas.

S-Kinoprene is not to be used through any type of irrigation system.

Regulatory History

S-Kinoprene was first registered as a pesticide in the U.S. in 1975 under the trade name Enstar®5E, and renamed Enstar®II, (EPA Reg. No. 55947-82) for use as an insecticide on indoor non-food/non-feed crops grown in greenhouses and nurseries. A Data Call-In was issued on September 30, 1993 to Sandoz Agro, Inc., the registrant for S-Kinoprene, requiring additional toxicity data to satisfy the genotoxicity requirement. Case No. 4117 also consists of R-S-Hydroprene (488300), and R-S Kinoprene (107501) which are no longer supported by the registrant. S-Hydroprene (128988) was registered in 1986. This decision includes a comprehensive reassessment of the required target data and the use patterns of the currently registered product.

Human Health Assessment

Toxicity

Adequate mammalian toxicology data are available to support reregistration of the active ingredient S-Kinoprene, and will support a Reregistration Eligibility Decision (RED)

Dietary Exposure

The uses of S-Kinoprene do not require a tolerance or an exemption from tolerance, and dietary exposure from the uses of S-Kinoprene is unlikely. Acute exposure from the proposed greenhouse and indoor use site may occur, but would be very low because of the low application rates.

On August 3, 1996, the food Quality Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA) 21, U.S.C. 301 et. seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances, but FQPA does not obligate the Agency to consider the factors set forth in the new section 408 of the FFDCA when making decisions under FIFRA with respect to pesticides that do not have any food uses. However, the FQPA did not amend any of the existing reregistration deadlines in section 4 of FIFRA.

EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process is likely to include an examination of whether the same or a similar safety standard should apply to non-food pesticide applications. Such a standard might include exposure of infants and children to the pesticide(s), cumulative effects on infants and children from this pesticide and other substances that have a common mechanism of toxicity, and aggregate exposure of the population and major subgroups of the population of the pesticide and related substances. The Agency has not yet determined with finality how it will make such decisions. However, in

light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intent to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determination described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

Available data indicate that residues of S-Kinoprene do not concentrate in processed food or feed; therefore, no food or feed additive tolerances are established or required.

Occupational and Residential

Based on the application methods, the potential for dermal eye, and inhalation exposures to S-Kinoprene for pesticide handlers and applicators exist. Because of the lack of significant mammalian toxicity, worker exposure data (i.e., occupational exposure data) to the active ingredient are not required at this time. However, due to the primary eye irritation response (Toxicity Category III) the Agency will require the appropriate Signal Word (Caution and Statements of Precaution (Causes slight eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling).

Based on the use sites, use patterns, application method, and use rates, the potential exposure to humans, including infants and children, is negligible.

Environmental Assessment

All ecological toxicity and environmental fate data requirements have been adequately satisfied according to the guidelines set forth in 40 CFR 158.690 for biochemical pesticides for non-food/non-feed use.

Ecological Toxicity Data

In the Phase IV review of S-Kinoprene, the Ecological Effects Branch (EEB), Environmental Fate and Effects Division (EFED), waived all non-target data requirements because “Based on the use patterns, exposure to non-target organisms is expected to be non-existent or negligible.” (March 30, 1993 Memorandum from Anthony F. Maciorowski to Bruce Sidwell).

An aquatic invertebrate toxicity study involving *Daphnia* recently has been submitted under FIFRA 6(a)(2). All data requirements for S-Kinoprene have been adequately fulfilled; no additional studies are required for these uses.

Environmental Fate

In the Phase IV review of S-Kinoprene, the Environmental Fate and Groundwater Branch (EFGWB) in the Environmental Fate and Effects Division, did not require any Environmental Fate data for S-Kinoprene based on the use-patterns and low application rates (May 15, 1993 Memorandum from E. Brinson Conerly-Parks to Bruce Sidwell). Currently, Environmental Fate data are not required for biochemical pesticides unless effects in Tier I non-target studies indicate fate studies would be needed (40 CFR 185.690).

Exposure and Risk Characterization

S-Kinoprene was considered "highly toxic" to *Daphnia Magna*. However, water insoluble material like S-Kinoprene might cause adverse effects to *Daphnia* based on the inherent design of the toxicity study (Guideline 154B-9). Since the use of S-Kinoprene is limited to greenhouses and interiorscapes and such use patterns are not expected to pose a significant risk to aquatic invertebrates, environmental fate studies will not be required. Rather, any potential effects will be further mitigated by including label language "do not contaminate water, food or feed by storage or disposal."

Additional Data Required

The generic data base supporting the reregistration of S-Kinoprene for the above eligible uses has been reviewed and determined to be substantially complete. Therefore, there are no further generic data requirements being imposed at this time.

Product Labeling Changes Required

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR ⁿ 156.10 and other applicable notices.

Use Sites: Registrants must specify on labeling the complete directions for use for each use pattern.

Application Rate: All labels must give specific maximum application rate, type of application, timing of application, equipment used for application, the rate of application (dosage), and maximum application rate.

Non-Food/Non-Feed Use: In conformity with S-Kinoprene's non-food/non-feed use, labels should read: "Do not contaminate water, food, or feed by storage or disposal."

The registrant must submit five (5) copies of the updated labeling and the updated Confidential Statement of Formula for each registered product.

Regulatory Conclusion

Based on the reviews of the generic data for the active ingredient S-Kinoprene, the Agency has sufficient information on the health effects of S-Kinoprene and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that S-Kinoprene products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans (including infants and children) or to the environment. Therefore, the Agency concludes that for products containing S-Kinoprene, all uses are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for S-Kinoprene during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the S-Kinoprene RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the S-Kinoprene RED, or reregistration of individual products containing S-Kinoprene, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.